

a'   
wel.

substantially equal to the thickness of said test strips.

---

REMARKS

Examiner's recent Office Action has been carefully considered and the patents cited therein as references have been closely studied. However, it is believed that applicant's invention is patentable over the prior art references taken either singly or in the combinations proposed by the Examiner. Accordingly, the original claims have all been canceled and applicant is submitting a set of new claims which have been carefully drafted to clearly and definitely recite applicant's invention and to define over the cited references, both singly and in the proposed combinations.

The subject application discloses and claims a drug of abuse immuno assay test card which is capable of being inserted longitudinally through an opening, usually a slit in the top of a container having a fluid sample therein, and carrying thereon a plurality of test strips so mounted that a first portion of the

test strips receives the fluid sample and a second portion of the test strips visually indicates presence or absence of a selected drug of abuse.

This test card is so constructed to avoid any contact between the tester, person carrying out the test, and the fluid sample to be tested. Thus, there is no necessity for any dispensing or application of the fluid sample to be tested by the tester onto a test strip. At the same time, the test card insures proper contact of the test strip with the fluid sample and facilitates reading of the visual results.

None of the cited references discloses or suggest such a drug test card wherein one or more immuno assay test strips are disposed between the front and rear surfaces of a thin flat member such that the ends of the test strips terminate short of the ends of the test card and are enclosed therein and access to the test strip by a pair of openings in the front surface of the test card spaced longitudinally to register with and expose the sample and test portions of each of the test strips. Thus each test strip is fully protected during insertion and withdrawal of the test card through the opening in the top of a container and human contact with the test strips on the test card is prevented

without the necessity for sealing or encasing the individual test strips.

With respect to the cited references, Lee-Own shows a test strip which is totally enclosed and sealed with a film or tape to provide a packaging pouch for the test strip. However, in order to use the Lee-Own test strip, additional procedures are necessary which include cutting off a portion of the package to expose an end of the test strip as shown at 16 in Fig. 1. Thus, the end of the test strip is not protected but forms an end of the package and both ends of the test strip are not spaced from the ends of the card. Lee-Own does not disclose or suggest an opening in the surface of his package spaced from the bottom of the package for receiving the fluid sample.

Sun, et al shows a test strip which is completely enclosed between two pieces of plastic that are welded together to fabricate a plastic housing of a test device. No portions of a test strip in this patent are exposed to the atmosphere through suitably arranged openings in a front surface of a test device. As shown in Fig. 1a, a surface of the plastic housing is provided with an opening 107 which is a reception cavity for the fluid sample to be tested and the fluid sample must then flow through a

passage 108 before coming into contact with test strip 102. Further, no portion of a test strip is exposed to the atmosphere to provide a visual indication of the test results until an outside sleeve 105 is moved longitudinally to reveal a view window area (which is not illustrated in the drawings). Thus, Sun also shows that an entire test device can be enclosed in a plastic holder but does not teach seating the test strip in a slotted recess between the front and rear surfaces of a test card nor does he suggest providing two openings on the surface of his package, a sample receiving opening and a viewing opening, as disclosed and claimed by applicant.

Davis shows an analytical specimen cup having a lid with spaced partitions therein to define a test space between the partitions and a test strip is mounted in this test space.

Of the above three references, only Lee-Own suggests the immersion of his test device into a sample. In Sun, the fluid sample is introduced to the opening in a face of the package and in Davis, the fluid sample is caused to flow into a chamber in the lid in which the test strip is mounted. It is thus believed to be rather unlikely that an ordinary practitioner would seek to combine any structural elements from Davis and Sun into the test

device of Lee-Own when the functions of each of these devices is wholly different from each other.

Boger shows a holder for accurately positioning and retaining multiple, individual reagent test devices. The holder is provided with a number of openings to expose each reagent area on the test strips for the application of a fluid sample. The ends of the test strips 20 project outwardly of the holder as clearly shown in Fig. 2 of the drawings. However, Boger is not at all concerned with the reading of the test results while the test strips are in the holder and, indeed, provides no such structure for doing this. In Boger, the strips are removed from the holder and then are checked for results. Thus, there is no suggestion in Boger of providing both sample receiving and test openings for each test strip and for enclosing the test strips within the outline of the holder. All of the openings 18 disclosed in Boger are intended only for the applications of samples. Further, while Boger suggests that the entire holder can be dipped into the sample to be tested, there is no provision or teaching of reading of the results of tests on the test strips until after the holder has been opened and the test strips have been removed therefrom.

Huang merely discloses a lateral flow test strip of a type

similar to that utilized in applicant's test card. He specifically states that this is a test strip without a plastic housing. This is the type of test strip which is mounted in applicant's test card in the manner as disclosed and claimed by applicant. Merely having this test strip in front of one skilled in the art would in no way suggest the mounting of this test strip in a test card as proposed by applicant since this patent is concerned only with the construction of this test strip, per se.

Norell shows a testing device 20 having testing elements for the analysis of a sample. The sample being tested is placed in well 30 in the back panel so as to contact the sample application pad 62 on test strip 60. The sample receiving portion is not open and exposed through the front panel but is covered by the absorbent pad 72.

The prior art thus shows a test device with openings to receive fluid samples and another form of test device having an opening to view the results. However, none of these cited references show a test card enclosing test strips and the front face of a test card has a first opening for the application of a sample to the test strip and a second opening for viewing the

results on the same test strip. There is nothing in the prior art to suggest such a structure or of combining elements selected from the prior art references to arrive at this structure as disclosed and claimed by applicant.

Applicant has thus succeeded in inventing a test card which is particularly adapted for insertion through an opening in the top of a container to contact a fluid sample within the container. This test card has in its front face an opening for the sample to contact a test strip and a second opening through which the results of the test on that test strip can be read. The test strips are enclosed within the test card so as to be completely protected while inserted in the slot and the only portions of the test strips visible are the sample receiving and test portions. No combination of the cited references teaches or even suggests this structure as invented by applicant.

Galloway, which has been made of record, is not at all pertinent to applicant's invention as disclosed and claimed since Galloway discloses a plurality of test strips 46 having their ends attached between a wick material 52 and an absorbent pad 60 and this arrangements of strips is then enclosed within a space defined by cover 48 and inner wall 30 of the container 12. This

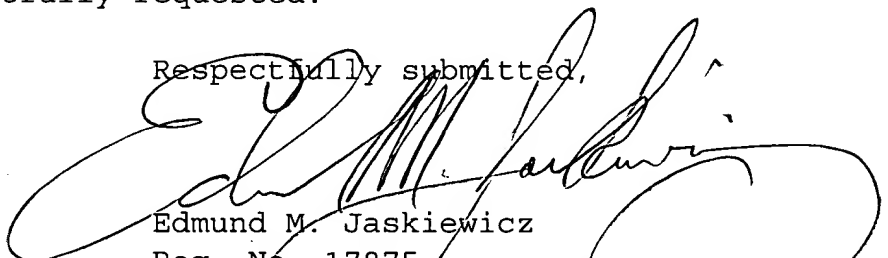
structure of the tests strips clearly does not teach or permit insertion into the container since the opening of the container is sealed by a cap 28 which has no openings whatsoever therein.

It is believed that the formal objections to the claims have been overcome by this set of new claims.

A Petition for Extension of Time together with the requisite fee is attached to this paper.

In view of the foregoing amendments and remarks, it is believed that the new claims in this case now clearly and definitely recite applicant's invention and define patentably over the cited references. An early and favorable response from the Examiner is respectfully requested.

Respectfully submitted,



Edmund M. Jaskiewicz  
Reg. No. 17875  
1730 M Street, N.W., Suite 400  
Washington, D.C. 20036  
(202) 296-2900